General

Guideline Title

Anaphylaxis: guidelines from the European Academy of Allergy and Clinical Immunology.

Bibliographic Source(s)

Muraro A, Roberts G, Worm M, BilÃ² MB, Brockow K, FernÃ¡ndez Rivas M, Santos AF, Zolkipli ZQ, Bellou A, Beyer K, Bindslev-Jensen C, Cardona V, Clark AT, Demoly P, Dubois AE, DunnGalvin A, Eigenmann P, Halken S, Harada L, Lack G, Jutel M, Niggemann B, RuÃ«ff F, Timmermans F, Vlieg-Boerstra BJ, Werfel T, Dhami S, Panesar S, Akdis CA, Sheikh A, EAACI Food Allergy and Anaphylaxis Guidelines Group. Anaphylaxis: guidelines from the European Academy of Allergy and Clinical Immunology. Allergy. 2014 Aug;69(8):1026-45. [132 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the level of the evidence (I–V) and grades of recommendation (A–D) are provided at the end of the "Major Recommendations" field.

Refer to the original guideline document for the following additional information: key terms used in this guideline (Box 1), clinical criteria for diagnosing anaphylaxis (Box 4), differential diagnosis of anaphylaxis (Box 5), examples of risk factors and cofactors of anaphylaxis (Box 6), checklist for managing anaphylaxis (Box 8), summary of the long-term management in the community of patients at risk of anaphylaxis (Box 9), example of an individualized anaphylaxis emergency action plan (Box 11), rate of usage of adrenaline auto-injectors by patients (Box 13), and anaphylaxis: gaps in the evidence (Box 15).

Emergency Management: Recommendations

First-Line Intervention: Adrenaline

- Adrenaline is potentially lifesaving and must therefore promptly be administered as the first-line treatment for the emergency management of anaphylaxis (Evidence level: IV; Grade: C) (Pumphrey, 2000; Pumphrey & Gowland, 2007; Bock, Munoz-Furlong, & Sampson, 2007; Bock, Munoz-Furlong, & Sampson, 2001; Soreide, Buxrud, & Harboe, 1988).
- Earlier administration of adrenaline should be considered on an individual basis when an allergic reaction is likely to develop into anaphylaxis (Evidence level: V; Grade: D) (Expert consensus).

- Adrenaline should be administered by intramuscular injection into the mid-outer thigh (Evidence level: I; Grade: B) (Simons et al., 1998; Simons, Gu, & Simons, 2001).
- In patients requiring repeat doses of adrenaline, these should be administered at least 5 min apart (Evidence level: V; Grade: D) (Simons, Gu, & Simons, 2001; Expert consensus).
- With inadequate response to two or more doses of intramuscular adrenaline, adrenaline may be administered as an infusion by appropriately experienced intensive care, emergency department, and critical care physicians, with appropriate cardiac monitoring (Evidence level: IV; Grade: D) (Soreide, Buxrud, & Harboe, 1988).

Second-Line Interventions

- Trigger of the anaphylaxis episode should be removed (Evidence level: V; Grade: D) (Expert consensus).
- Help should be called promptly and simultaneously with patient's assessment (Evidence level: V; Grade: D) (Expert consensus).
- Patients experiencing anaphylaxis should be positioned supine with elevated lower extremities if they have circulatory instability, sitting up if they have respiratory distress, and in recovery position if unconscious (Evidence level: V; Grade: D) (Pumphrey & Gowland, 2007).
- High-flow oxygen should be administered by face mask to all patients with anaphylaxis (Evidence level: V; Grade: D) (Expert consensus).
- Intravenous fluids (crystalloids) should be administered (boluses of 20 ml/kg) in patients experiencing cardiovascular instability (Evidence level: V; Grade: D) (Expert consensus).
- Inhaled short-acting beta-2 agonists should additionally be given to relieve symptoms of bronchoconstriction (Evidence level: V; Grade: D) (Pumphrey, 2000).

Third-Line Interventions

- Oral H1- (and H2)-antihistamines may relieve cutaneous symptoms of anaphylaxis (Evidence level: I; Grade: B) (Runge et al., 1992; Lin et al., 2000).
- Systemic glucocorticosteroids may be used as they may reduce the risk of late-phase respiratory symptoms. High-dose nebulized glucocorticoids may be beneficial for upper airway obstruction (Evidence level: V; Grade: D) (Expert consensus).

Monitoring and Discharge

- Patients who presented with respiratory compromise should be closely monitored for at least 6–8 h, and patients who presented with circulatory instability require close monitoring for 12–24 h (Evidence level: V; Grade: D) (Expert consensus).
- Before discharge, the risk of future reactions should be assessed and an adrenaline auto-injector should be prescribed to those at risk of recurrence (Evidence level: V; Grade: D) (Expert consensus).
- Patients should be provided with a discharge advice sheet, including allergen avoidance measures (where possible) and instructions for the use of the adrenaline auto-injector. Specialist and food allergy specialist dietitian (in food anaphylaxis) follow-up should be organized. Contact information for patient support groups should also be provided (Evidence level: V; Grade: D) (Expert consensus).

Long-Term Management: Recommendations

Anaphylaxis Management Plan

- An anaphylaxis management plan should be used from the time of diagnosis to prevent future reactions, and aid recognition and treatment of any further reactions (Evidence level: III; Grade: C) (Ewan & Clark, 2005; Kapoor et al., 2004).

Venom Immunotherapy (VIT)

- Subcutaneous VIT is recommended in venom-allergic patients with a previous episode of anaphylaxis and adults with systemic cutaneous reactions (Evidence level: I; Grade: A) (Golden et al., 2011; Boyle et al., 2012; Ross, Nelson, & Finegold, 2000; Watanabe et al., 2010; Hockenhull et al., 2012).

Training

- Training in the recognition and management of anaphylaxis should be offered to all patients and caregivers of children at risk of anaphylaxis ideally from the time of diagnosis (Evidence level: V; Grade D) (Muraro et al., 2007; Simons et al., 2011)
- Training in the recognition and management of anaphylaxis, including the use of adrenaline auto-injectors, should be offered to all professionals dealing with patients at risk of anaphylaxis (Evidence level: IV; Grade: C) (Sicherer, Forman, & Noone, 2000)
- Training packages should be developed with the target groups (Evidence level: V; Grade: D) (Expert consensus).
- Training should cover allergen avoidance, symptoms of allergic reactions, when and how to use an adrenaline auto-injector, and what other measures are needed within the context of an anaphylaxis management plan (Evidence level: V; Grade: D) (Muraro et al., 2007; Simons et

al., 2011; Ewan & Clark; 2005; Vickers, Maynard, & Ewan, 1997).
- Training may involve more than one session to allow revision, an interactive scenario-based approach, a standardized program with manual and educational material and simulation tools. Content and language should be tailored to be understood and memorized (Evidence level: V; Grade: D) (Muraro et al., 2007; Patel, Bansal, & Tobin, 2006).

Psychological Interventions

- Educational interventions should ideally incorporate psychological principles and methods to address anxiety so that children and families may function well at home, at school/work, and socially despite their risk of future reactions and should ideally be part of their educational training. This can be done in a group format. Some patients, with severe anxiety of ongoing duration, may need more in-depth one-to-one psychological intervention (Evidence level: V; Grade: D) (DunnGalvin, Gaffney, & Hourihane, 2009: Manassis, 2012; Akeson, Worth, & Sheikh, 2007).

Indications for Prescription of an Adrenaline Auto-injector

Absolute Indications for at Least One Adrenaline Auto-injector

- Previous anaphylaxis triggered by food, latex, or aeroallergens (Evidence level: IV; Grade: C) (Anagnostou et al., 2012; Hourihane et al., 1997)
- Previous exercise-induced anaphylaxis (Evidence level: IV; Grade: C) (Shadick et al., 1999)
- Previous idiopathic anaphylaxis (Evidence level: IV; Grade: C) (Noimark et al., 2012)
- Co-existing unstable or moderate to severe, persistent asthma and a food allergy* (Evidence level: IV; Grade: C) (Simons, Clark, & Camargo, 2009; Uguz et al., 2005; Jarvinen et al., 2008; Manivannan et al., 2009; Rudders et al., 2010)
- Venom allergy in adults with previous systemic reactions (not receiving maintenance VIT) and children with more than cutaneous/mucosal systemic reactions (Evidence level: IV; Grade: C) (Golden et al., 2011; Bonifazi et al., 2005; Krishna et al., 2011)
- Underlying mast cell disorders or elevated baseline serum tryptase concentrations together with any previous systemic allergic reactions to insect stings, even in VIT-treated patients (Evidence level: IV; Grade: C) (Rueff et al., 2009; Golden et al., 2011; Tramer et al., 2006; Krishna et al., 2011)

Consider Prescribing at Least One Adrenaline Auto-injector with Any of the Following Additional Factors (Especially If More Than One Is Present)

- Previous mild-to-moderate allergic reaction* to peanut and/or tree nut (Evidence level: IV; Grade: C) (Vander Leek et al., 2000; Ewan & Clark, 2005)
- Teenager or young adult with a food allergy* (Evidence level: IV; Grade: C) (Pumphrey, 2000; Pumphrey & Gowland, 2007; Bock, Munoz-Furlong, & Sampson, 2007; Bock, Munoz-Furlong, & Sampson, 2001; Sicherer & Simons, 2005)
- Remote from medical help and previous mild-to-moderate allergic reaction to a food, venom, latex, or aeroallergens (Evidence level: V; Grade: D) (Sicherer & Simons, 2005; Expert consensus)
- Previous mild-to-moderate allergic reaction to traces of food* (Evidence level: V; Grade: D) (Pumphrey, 2000; Pumphrey & Gowland, 2007; Bock, Munoz-Furlong, & Sampson, 2007; Bock, Munoz-Furlong, & Sampson, 2001; Sicherer & Simons, 2005)

Suggested Indications for Prescription of a Second Adrenaline Auto-injector

Suggested Indications for Prescribing a Second Auto-injector for the Patient to Carry Include:

- Co-existing unstable or moderate to severe, persistent asthma and a food allergy* (Evidence level: IV; Grade: C) (Jarvinen et al., 2008)
- Co-existing mast cell diseases and/or elevated baseline tryptase concentration (Evidence level: IV; Grade: C) (Bonifazi et al., 2005; Krishna et al., 2011)
- Lack of rapid access to medical assistance to manage an episode of anaphylaxis due to geographical or language barriers (Evidence level: V; Grade: D) (Expert consensus)
- Previous requirement for more than one dose of adrenaline prior to reaching hospital (Evidence level: V; Grade: D) (Expert consensus)
- Previous near fatal anaphylaxis (Evidence level: V; Grade: D) (Expert consensus)
- If available auto-injector dose is much too low for body weight (Evidence level: V; Grade: D) (Expert consensus)

*Excluding pollen food syndrome (oral allergy syndrome).

Definitions:

Level of Evidence

Level I	Systematic reviews, meta-analysis, randomized controlled trials
Level II	Two groups, nonrandomized studies (e.g., cohort, case–control)
Level III	One group nonrandomized (e.g., before and after, pretest, and post-test)
Level IV	Descriptive studies that include analysis of outcomes (single-subject design, case series)
Level V	Case reports and expert opinion that include narrative literature, reviews, and consensus statements

Grades of Recommendation

Grade A	Consistent level I studies
Grade B	Consistent level II or III studies or extrapolations from level I studies
Grade C	Level IV studies or extrapolations from level II or III studies
Grade D	Level V evidence or troublingly inconsistent or inconclusive studies at any level

Clinical Algorithm(s)

An algorithm titled "Schematic Illustration of the Initial Management of Anaphylaxis" is provided in the original guideline document.

Scope

Disease/Condition(s)

Anaphylaxis

Guideline Category

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Allergy and Immunology

Critical Care

Emergency Medicine

Family Practice

Internal Medicine

Pediatrics

Pulmonary Medicine

Intended Users

Advanced Practice Nurses

Emergency Medical Technicians/Paramedics

Health Care Providers

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide evidence-based recommendations for the recognition, risk factor assessment, and the management of patients who are at risk of, are experiencing, or have experienced anaphylaxis

Target Population

Patients who have experienced, are experiencing, or are at risk of experiencing anaphylaxis

Interventions and Practices Considered

1. Emergency management
    - First-line intervention: adrenaline
    - Second-line interventions
        - Removing trigger of anaphylaxis episode
        - Prompt call for help
        - Patient positioning
        - High-flow oxygen administration by face mask
        - Intravenous fluids (crystalloids)
        - Inhaled short-acting beta-2 agonist
    - Third-line interventions
        - Oral H1- (and H2)-antihistamines
        - Systemic glucocorticosteroids
    - Monitoring and discharge, including discharge advice sheet
2. Long-term management
    - Anaphylaxis management plan
    - Subcutaneous venom immunotherapy (VIT)
    - Training in the recognition and management of anaphylaxis, including use of adrenaline auto-injectors
    - Psychological interventions
3. Prescription of an adrenaline auto-injector
    - Absolute indications for prescribing at least one adrenaline auto-injector
    - Suggested indications for prescribing a second auto-injector

Major Outcomes Considered

- Effectiveness of pharmacological and nonpharmacologial interventions for acute and long-term management of anaphylaxis
- Incidence rate of anaphylaxis
- Point prevalence, period prevalence, and lifetime prevalence of anaphylaxis

- Risk factors for anaphylaxis
- Case-fatality rate

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

The development of these guidelines has been underpinned by two systematic reviews of the literature, both on the epidemiology and on clinical management of anaphylaxis (see the "Availability of Companion Documents" field).

Systematic Reviews of the Evidence

The initial full range of questions that were considered important were rationalized through several rounds of iteration to agree to three key questions that were then pursued through the two formal systematic reviews of the evidence. Key questions addressed in the two supporting systematic reviews:

- What is the epidemiology (i.e., frequency, risk factors, and outcomes) of anaphylaxis and how do these vary by time, place, and person?
- What is the effectiveness of interventions for the acute management of anaphylaxis?
- What is the effectiveness of interventions for the long-term management of those at high risk of further episodes of anaphylaxis?

The Epidemiology of Anaphylaxis in Europe: a Systematic Review

Search Strategies

To retrieve systematic reviews, reviewers used the systematic review filter developed at McMaster University Health Information Research Unit (HIRU) (http://hiru.mcmaster.ca/hiru/HIRU_Hedges_MEDLINE_Strategies.aspx#Reviews). Reviewers also adapted the search filter from York University Centre for Reviews and Dissemination (http://www.york.ac.uk/inst/crd/intertasc/epidemiological_studies.html) to retrieve incidence, prevalence, and other characteristics describing the epidemiology of anaphylaxis. Similarly, the McMaster filter for prognosis studies was also applied (http://hiru.mcmaster.ca/hiru/HIRU_Hedges_EMBASE_Strategies.aspx#Prognosis).

The following databases were searched: MEDLINE (OVID), EMBASE (OVID), CINAHL (Ebscohost) and ISI Web of Science (Thomson Web of Knowledge). The search strategy was devised on OVID MEDLINE and then adapted for the other databases (see Boxes E1-4 in the online supplement of the systematic review [see the "Availability of Companion Documents" field]). In all cases, the databases were searched from January 1, 2000 to September 30, 2012. Searches were limited to literature from 2000 onwards because the reviewers wanted to understand and describe the contemporary epidemiology of anaphylaxis, and ensure a pragmatic approach to dealing with the vast body of literature. Given the scope of the European guidelines, the search was limited to European evidence. European countries were based on the definitions provided by the Organisation for Economic Co-operation and Development (OECD) (http://www.oecd.org/std/oecdmaineconomicindicators-countriescovered.htm), i.e., Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom (UK). All references were collated into an EndNote Library and tagged with the name of the database. Additional references were located through searching the references cited by the identified studies, and unpublished work, and research in progress was identified through discussion with experts in the field. Experts who are active in the field from a range of disciplines and geography were also invited to comment on the search strategy, and the list of included studies. There were no language restrictions and, where possible, all literature was translated.

Inclusion Criteria for Study Design

The following studies were included: systematic reviews ±meta-analyses, cohort studies, cross-sectional studies, case–control studies, and routine healthcare studies. These were chosen to ensure that the highest levels of evidence were pooled based on the aims of this review.

Exclusion Criteria for Study Design

Reviews, discussion papers, nonresearch letters and editorials, case studies, and case series plus animal studies were excluded.

Study Selection

The titles of the retrieved articles were checked independently by two reviewers according to the selection criteria and categorized as included, not included, and unsure. The abstracts of unsure category papers were retrieved, and they were recategorized after discussion. Any discrepancies were resolved by consensus, and if necessary, a third reviewer was consulted to arbitrate. Full-text copies of potentially relevant studies were obtained and their eligibility for inclusion assessed.

Management of Anaphylaxis: a Systematic Review

Search Strategy

A highly sensitive search strategy was designed to retrieve all articles combining the concepts of anaphylaxis and epidemiology from electronic bibliographic databases. Reviewers focused on the acute management of anaphylaxis by assessing the effectiveness of epinephrine, H1-antihistamines (versus placebo), systemic glucocorticosteroids, methylxanthines or any other treatments for the emergency management of people experiencing anaphylaxis. The main interventions that have been studied in the context of long-term management are anaphylaxis management plans and allergen-specific immunotherapy.

Inclusion Criteria for Study Design

In summary, the inclusion criteria were systematic reviews with or without meta-analyses, randomized controlled trials (RCTs), quasi-RCTs, controlled clinical trials (CCTs), controlled before-after (CBA) designs, interrupted time series (ITS) studies, and case-series, with a minimum of 10 patients, for studies investigating the use of adrenaline.

The evidence was appraised by preferentially looking at higher levels of evidence such as systematic reviews and/or meta-analyses of RCTs and individual RCTs. However, in view of the anticipated limited information available, it was decided *a priori* to include systematic reviews that included other non-RCT study designs (focusing on the studies that had used Effective Practice and Organisation of Care [EPOC])-endorsed study designs); quasi-RCTs and CCTs (i.e., where non-random allocation of patients had occurred); other EPOC study designs such as CBA studies (i.e., those in which observations were made before and after the implementation of an intervention) and ITS (i.e., where observations were made at multiple time-points before and after the intervention). Despite their representing much weaker forms of evidence, case series were eligible for inclusion in relation to adrenaline as expert advice pointed to the considerable ethical, scientific and logistical difficulties in mounting more rigorous study designs.

Exclusion Criteria for Study Design

Reviews, discussion papers, non-research letters and editorials and case studies plus animal studies were excluded.

Study Selection

The titles were independently checked by two reviewers according to the above criteria; any discrepancies were resolved by consensus and when necessary a third reviewer was consulted.

Number of Source Documents

The Epidemiology of Anaphylaxis in Europe: a Systematic Review

The searches identified a total of 5843 potentially eligible studies, of which 49 satisfied the eligibility criteria and were therefore included in the review.

Management of Anaphylaxis: a Systematic Review

The searches identified a total of 8929 potentially eligible studies, of which 55 satisfied the eligibility criteria and were therefore included in the

review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level I	Systematic reviews, meta-analysis, randomized controlled trials
Level II	Two groups, nonrandomized studies (e.g., cohort, case–control)
Level III	One group nonrandomized (e.g., before and after, pretest, and post-test)
Level IV	Descriptive studies that include analysis of outcomes (single-subject design, case series)
Level V	Case reports and expert opinion that include narrative literature, reviews, and consensus statements

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The development of these guidelines has been underpinned by two systematic reviews of the literature, both on the epidemiology and on clinical management of anaphylaxis (see the "Availability of Companion Documents" field).

The Epidemiology of Anaphylaxis in Europe: a Systematic Review

Quality Assessment Strategy

Each study was quality-assessed independently by two reviewers using the relevant version of the Critical Appraisal Skills Programme (CASP) quality assessment tool for systematic reviews, cohort studies, and case–control studies, which involved an assessment of internal and external validity. Similarly, reviewers used the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for assessing other forms of quantitative studies such as cross-sectional studies and routine healthcare studies. Any discrepancies were resolved by discussion or, where necessary, by arbitration by a third reviewer.

Analysis, Data Synthesis, and Reporting

Data were independently extracted onto a customized data extraction sheet by two reviewers, and any discrepancies were resolved by discussion or, where necessary, by arbitration by a third reviewer. A descriptive summary with data tables was produced to summarize the literature. Meta-analysis was undertaken using random-effects modeling and adopting methods suggested by Agresti and Coul. Heterogeneity was assessed using Cochrane's Q, a statistic based on the chi-square test with corresponding Z- and p-values. As this test is known to have low power, the chi-square statistic was also calculated: a value of 25% corresponds to low heterogeneity, 50% to moderate, and 75% to high. Comprehensive meta-analysis (Biostat, Englewood, NJ, USA) was used for these analyses. A narrative synthesis of the data was also undertaken. The PRISMA checklist was used to guide the reporting of the systematic review.

Management of Anaphylaxis: a Systematic Review

Quality Assessment

Quality assessments of studies were undertaken using the relevant version of the CASP quality assessment tool for systematic reviews. Reviewers

assessed the risk of bias of studies eligible for the review using the criteria suggested by Effective Practice and Organisation of Care (EPOC). Randomized controlled trials (RCTs), controlled clinical trials (CCTs) and controlled before-after trials (CBAs) were assessed for: generation of allocation sequence; concealment of allocation; baseline outcome measurements; baseline characteristics; incomplete outcome data; blinding of outcome assessor; protection against contamination; selective outcome reporting; and other risks of bias. These assessments drew on the principles incorporated into the Cochrane EPOC guidelines for assessing intervention studies and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) for assessing observational studies. Similarly, reviewers drew on the quality assessment tool produced by the National Institute for Health and Clinical Excellence (NICE) to help critically appraise case series.

Analysis, Data Synthesis and Reporting

All assessments and data extraction were carried out independently by two reviewers; any discrepancies were resolved through discussion amongst the reviewers and, where necessary, arbitration by a third reviewer. A descriptive summary with data tables was produced to summarize the literature. Reviewers preferentially extracted data on risk ratios and mean differences. Data were not suitable for meta-analysis so a narrative synthesis of the data is reported.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These guidelines were produced using the Appraisal of Guidelines for Research & Evaluation (AGREE II) approach, a structured approach to guideline production. This is designed to ensure appropriate representation of the full range of stakeholders, a careful search for and critical appraisal of the relevant literature, a systematic approach to the formulation and presentation of recommendations, and steps to ensure that the risk of bias is minimized at each step of the process. The process began in January 2012, ensuing over 18 months, with in detail discussion of the frame of guidelines for clinical practice, the main aims of the guidelines, the target conditions, agreeing the intended end-user for the recommendations, agreeing the intended end-user group, and ensuring adequate professional and lay representation in the guidelines development process. The process involved:

Clarifying the Scope and Purpose of the Guidelines

The scope of these European Academy of Allergy and Clinical Immunology (EAACI) guidelines is multifaceted providing statements that assist clinicians in the management of anaphylaxis in daily practice; harmonizing the approach to this clinical emergency among stakeholders across Europe; and advocating for further research.

Ensuring Appropriate Stakeholder Involvement

Participants in the Anaphylaxis Taskforce represented a range of 14 European countries, and disciplinary and clinical backgrounds, for example emergency physicians, primary care, patient groups, and dietitians.

Systematic Reviews of the Evidence

The initial full range of questions that were considered important were rationalized through several rounds of iteration to agree to three key questions that were then pursued through two formal systematic reviews of the evidence.

Formulating Recommendations

The Taskforce members graded the strength and consistency of key findings from these systematic reviews to formulate evidence-linked recommendations for care (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields). This involved formulating clear recommendations and making clear the strength of evidence underpinning each recommendation. Experts identified the resource implications of implementing the recommendations, barriers, and facilitators to the implementation of each recommendation, advice on approaches to implementing the recommendations and suggested audit criteria that can help with assessing organizational compliance with each recommendation (see Supporting Information Tables S1 and S2 [see the "Availability of Companion Documents" field]).

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Grade A	Consistent level I studies
Grade B	Consistent level II or III studies or extrapolations from level I studies
Grade C	Level IV studies or extrapolations from level II or III studies
Grade D	Level V evidence or troublingly inconsistent or inconclusive studies at any level

Cost Analysis

One systematic review investigated the clinical and cost-effectiveness of a specific venom immunotherapy (VIT) subcutaneous preparation (Pharmalgen, ALK-Abello, Reading, UK) and included nine trials (four randomized controlled trials [RCTs] and five quasi-RCTs), all judged to be of poor quality. The authors modelled cost-effectiveness showing a cost of £8–20 (€10–25) million/life year gained, assuming a base-case scenario of no improvement in quality of life. A sensitivity analysis showed that VIT was more cost-effective in those at high risk of further stings or if improvements in quality of life and anxiety associated with VIT were included in the model.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review and Public Comment

A draft of these guidelines was externally peer-reviewed by invited experts from a range of organizations, countries, and professional backgrounds. Additionally, the draft guidelines were made available on the European Academy of Allergy and Clinical Immunology (EAACI) Web site for a 3-week period in July 2013 to allow all stakeholders to comment. All feedback was considered by the Anaphylaxis Taskforce and, where appropriate, final revisions were made in light of the feedback received. The guideline authors will be pleased to continue to receive feedback on these guidelines, which should be addressed to the corresponding author.

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Recognition and appropriate management of patients who are at risk of, are experiencing, or have experienced anaphylaxis

Potential Harms

- The safety profile of intramuscular adrenaline is excellent although patients may experience transient pallor, palpitations, and headache. Adrenaline infusion must be given by those experienced in the use of vasopressors in their daily clinical practice, for example anesthetists, emergency department (ED), and critical care doctors. Intravenous adrenaline in patients with adequate circulation may cause life-threatening hypertension, myocardial ischemia, and arrhythmias. Patients who are given intravenous adrenaline should be monitored with continuous electrocardiogram (ECG), pulse oximetry, and frequent noninvasive blood pressures. There are no absolute contraindications to treatment with adrenaline in a patient experiencing anaphylaxis; benefits outweigh the risks in the elderly and patients with pre-existing cardiovascular disease.
- Rush protocols (i.e., over a few days) of venom immunotherapy (VIT) are as equally efficacious as slower regimens. More adverse effects have been reported with an ultra-rush (few hours) compared to a rush protocol and with rush compared to cluster protocols.
- Information about the future risk of anaphylaxis may lead to stress and anxiety in patients and caregivers. Research suggests that this should be addressed by alleviating uncertainty using psychological principles and methods to maximize quality of life as part of the educational training.

Implementation of the Guideline

Description of Implementation Strategy

Experts identified the resource implications of implementing the recommendations, barriers, and facilitators to the implementation of each recommendation, advice on approaches to implementing the recommendations and suggested audit criteria that can help with assessing organizational compliance with each recommendation. Additional supporting information may be found in the online version of this article (see the "Availability of Companion Documents" field):

- Table S1. Emergency management recommendations: barriers and facilitators to implementation, audit criteria and resource implications of recommendations.
- Table S2. Long-term management recommendations: barriers and facilitators to implementation, audit criteria and resource implications of recommendations.
- Table S3. Training recommendations: barriers and facilitators to implementation, audit criteria and resource implications of recommendations.
- Table S4. Psychological intervention recommendations: barriers and facilitators to implementation, audit criteria and resource implications of recommendations.

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Muraro A, Roberts G, Worm M, BilÃ² MB, Brockow K, FernÃ¡ndez Rivas M, Santos AF, Zolkipli ZQ, Bellou A, Beyer K, Bindslev-Jensen C, Cardona V, Clark AT, Demoly P, Dubois AE, DunnGalvin A, Eigenmann P, Halken S, Harada L, Lack G, Jutel M, Niggemann B, RuÃ«ff F, Timmermans F, Vlieg-Boerstra BJ, Werfel T, Dhami S, Panesar S, Akdis CA, Sheikh A, EAACI Food Allergy and Anaphylaxis Guidelines Group. Anaphylaxis: guidelines from the European Academy of Allergy and Clinical Immunology. Allergy. 2014 Aug;69(8):1026-45. [132 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Aug

Guideline Developer(s)

European Academy of Allergy and Clinical Immunology - Medical Specialty Society

Source(s) of Funding

The production of these guidelines was funded and supported by the European Academy of Allergy and Clinical Immunology (EAACI). The funder did not have any influence on the guidelines production process, on its contents, or on the decision to publish.

Guideline Committee

European Academy of Allergy and Clinical Immunology (EAACI) Taskforce on Anaphylaxis

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Financial Disclosures/Conflicts of Interest

Taskforce members' conflict of interests were taken into account by the Taskforce Chair as recommendations were formulated.

Conflicts of Interest

Graham Roberts has provided scientific advice for Danone and ALK-Abelló; Thermo Fisher and ALK-Abelló have provided consumables for his research activities. Antonella Muraro has provided scientific advice for Meda. Margitta Worm has provided scientific advice for ALK-Abelló. M. Beatrice Bilò has provided scientific advice for Meda. Knut Brockow has provided scientific advice for ALK-Abelló, Meda, Thermo Fisher, and Stallergenes. Montserrat Fernández Rivas has provided scientific advice to GSK; ALK-Abellóhas provided consumables for her research activities. Carsten Bindslev-Jensen has received funding from Thermo Fisher, HAL, Stallergenes, and Anergis, ALK, Novartis, MSD, Schering-Plough for his research activities. Victoria Cardona has provided scientific advice for ALK-Abelló. Pascal Demoly has provided scientific advice for Stallergenes, ALK-Abelló, Circassia, Allergopharma, Chiesi, Menarini, and Pierre Fabre Médicament; Tony DuBois has provided scientific advice for ALK-Abelló and received funding from ALK-Abelló to support his research activities. Audrey DunnGalvin has received funding from Novartis for her research. Philippe Eigenmann has provided scientific advice for Danone, Novartis, ALK, DBV technologies, and Stallergenes; he has received funding for research activities from LETI, Nestlé, and Thermo Fisher. Susanne Halken has provided scientific advice for ALK-Abelló. Marek Jutel has been an investigator for clinical studies led by Allergopharma, Stallergenes, Novartis, GSK, and Medimmune. Franziska RuÑ‘ff has been an investigator for clinical studies led by Allergopharma, HAL, Novartis, and Pierre Fabre and has received travel grants and honoraria as a speaker from ALK-Abelló, Bencard, HAL, Novartis, and Thermo Fisher. Frans Timmermans has received unrestricted grants from ALK-Abelló, MSD, MEDA for the activities of European Anaphylaxis Taskforce – Nederlands Anafylaxis Netwerk which he manages. Berber Vlieg–Boerstra has provided scientific advice for Danone and Mead Johnson; she has received research grants from Nutricia Advanced Medical Nutrition and ALK-Abelló. Sukhmeet Panesar, Sangeeta Dhami, and Aziz Sheikh have received funding for coordinating guidelines production and generating the systematic reviews from EAACI. Aziz Sheikh has provided scientific advice to ALK-Abelló, Meda, Lincoln Medical, Thermo Fisher, Pfizer, and Stallergenes; he is on the Anaphylaxis Campaign UK's Scientific Committee, World Allergy Organization's Anaphylaxis Special Committee, UK Resuscitation Council's Anaphylaxis Committee, and the BSACI's Standard of Care Committee. Laurie Harada works for Anaphylaxis Canada whose educational activities have been supported by Pfizer and Sanofi. Alexandra F. Santos, Zaraquiza Zolkipli, Cezmi Akdis, Kirsten Beyer, Abdul Bellou, Gideon Lack, Bodo Niggemann, Andy Clark, and Thomas Werfel have no conflict of interests.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Allergy Journal Web site .

Availability of Companion Documents

The following are available:

- Anaphylaxis: guidelines from the European Academy of Allergy and Clinical Immunology. Supporting information. Electronic copies: Available from the Allergy Journal Web site .
- Dhami S, Panesar SS, Roberts G, Muraro A, Worm M, Bilò MB, Cardona V, Dubois AEJ, DunnGalvin A, Eigenmann P, Fernandez-Rivas M, Halken S, Lack G, Niggemann B, Rueff F, Santos AF, Vlieg-Boerstra B, Zolkipli ZQ, Sheikh A on behalf of the EAACI Food Allergy and Anaphylaxis Guidelines Group. Management of anaphylaxis: a systematic review. Allergy 2014 Feb;69(2):168–175. Electronic copies: Available from the Allergy Journal Web site .
- Management of anaphylaxis: a systematic review. Supplemental information. Electronic copies: Available from the Allergy Journal Web site .
- Javad S, de Silva D, Nwaru BI, Hickstein L, Muraro A, Roberts G, Worm M, Bilò MB, Cardona V, Dubois AEJ, Dunn Galvin A, Eigenmann P, Fernandez-Rivas M, Halken S, Lack G, Niggemann B, Santos AF, Vlieg-Boerstra BJ, Zolkipli ZQ, Sheikh A on behalf of the EAACI Food Allergy and Anaphylaxis Group. The epidemiology of anaphylaxis in Europe: a systematic review. Allergy 2013 Nov;68(11):1353–1361. Electronic copies: Available from the Allergy Journal Web site .

- The epidemiology of anaphylaxis in Europe: a systematic review. Supplemental information. Electronic copies: Available from the Allergy Journal Web site .

Patient Resources

None available

NGC Status

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